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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,867	04/25/2005	Jorg Mayer	FRG-15988	6217
40854	7590	01/07/2009		
RANKIN, HILL, & CLARK LLP			EXAMINER	
38210 Glenn Avenue			SRIVASTAVA, TARUN K	
WILLOUGHBY, OH 44094-7808				
			ART UNIT	PAPER NUMBER
			3732	
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			01/07/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/528,867

**Applicant(s)**

MAYER ET AL.

**Examiner**

TARUN K. SRIVASTAVA

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6, 10-12, 16-20, 23-26 and 28-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 10-12, 16-20, 23-26 and 28-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Drawings***

1. The drawings were received on 07/30/2008. These drawings are accepted by the examiner.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Young (of record).

Young teaches an oscillation device (20) able to promote tissue regeneration on wound surfaces including an amplitude/direction changing ring shaped element 10 with a plurality of coupling means 30 that can be selectively coupled to an oscillation drive that is able to be coupled to a wound surface with the aid of an implant, and selecting a plurality of different amplitude/direction changing elements with a plurality of coupling locations (figure 6). In addition, Young teaches the amplitude/direction changing ring shaped element 10 to be ring shaped.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 17, 18, 34, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Bory (of record)

Young discloses the invention substantially as discussed above, but he fails to disclose the treatment element to be fastened on the outside surface of an opposing opening surface of the directing element.

Bory does teach a treatment element projecting from the opposing opening 42 (see figure 4). Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to modify Young's invention by including the projecting transforming element from the opposing opening of the surface of the directing elements', in order to render it less invasive.

7. Claims 20, 23, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klapper in view of Chiarizzio (of record).

Klapper discloses the invention substantially as claimed as discussed above, but fails to disclose the tips and edges projecting from the contact surface in an axial manner.

Chiarizzio does teach tips and edges 602 projecting from the contact surface axially. Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to incorporate Chiarizzio's tips and edges, in order to make the device less invasive.

8. Claims 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klapper in view of Chiarizzio, and further in view of Munch (of record).

Klapper/Chiarizzio disclose the invention substantially as claimed as discussed above, but fail to disclose the cylindrical or conical regions with increasing distance.

However, Munch does teach cylindrical and conical region 3 projecting from the treatment surface. Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to modify Klapper/Chiarizzio's invention by incorporating Munch's cylindrical or conical regions in order to more easily embed the device in the wound surface.

9. Claims 1 – 4, 6, 28 – 33 and 10 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bock (of record).

Bock teaches a method of promoting tissue regeneration on wound surfaces using: A cutting device 1 that is coupled with mechanical ultrasonic oscillation 3 and is stationary or moving and directly placed into a wound surface; wherein a coupling medium is applied between the treatment instrument and

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wound surface, wherein an amplitude – transforming element (piezoelectric transducer 20) is arranged between the instrument and the oscillation drive.

Bock adequately discloses the invention as claimed as discussed above, but fails to explicitly teach: a device with plurality of coupling locations, a frequency range of 1 kHz – 200 khz, and moving the device into a final implanted position when coupling the device to the wound surface.

Regarding the plurality of coupling locations, it would have been obvious to one having ordinary skill in the art to modify Bock's method of using a device with one coupling location to using Bock's method with a device having several coupling locations in order to make the procedure more convenient.

With respect to the range of frequencies, the instant disclosure describes the range as being merely preferable, and does not describe it as contributing any unexpected result to the method. As such, this parameter is deemed a matter of design choice (lacking in any criticality), well within the skill of the ordinary artisan, and obtained through routine experimentation in determining optimum results.

With respect to the final implanting location, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to incorporate a step of implanting the device into a wound surface in order to make the device more efficient and more convenient for the practitioner.

10. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Klapper (of record).

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11. Young discloses the oscillation device substantially as claimed, as discussed above, but fails to teach energy directors.

12. However, Klapper teaches an oscillation device 36 with a proximal coupling surface 39 for contacting wound surfaces provided with energy directors (figure 1). It would have been obvious to one having ordinary skill in the art, at the time the invention was made, to modify Young's oscillation device by incorporating Klapper's energy directors, in order to get a more complete scan of the entire wound surface.

### ***Response to Arguments***

13. Applicant's arguments filed 07/30/2008 have been fully considered but they are not persuasive.

Examiner would like to thank Applicant for the careful consideration of the application and the proper handling of formal matters. Objections and rejections to that extent have been withdrawn, in accordance with the filed amended claims, specification, and drawings.

Regarding the ring element 10, Examiner respectfully disagrees with Applicant's statement that it is incapable of acting as a 'direction transforming' element. Examiner maintains that any transducer or annular member will change direction, i.e. the direction vectors of a circular movement will constantly change direction, thus the annular member 10 in combination with the transducer, taught by Young, will definitely be a 'direction transforming' element. The same reasoning applies to Applicant's remarks regarding Bory.

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With respect to Applicant's assertion that Klapper's transducer does not transform oscillation amplitude, Examiner would like to point out that any transducer is capable of changing amplitude, as the vibrations and oscillations do not necessarily have to follow a uniform frequency. Further, the coupling surface 39 is CAPABLE of being coupled to a wound surface, thus Klapper has properly been used to reject the claim.

Addressing Applicant's argument that Bock does not teach a plurality of coupling locations, this argument is moot, as Examiner has deemed Applicant's invention obvious over Bock, thus it is only required that an obvious step have been taken to reach Applicant's invention from Bock. In the present case, incorporating several coupling locations as opposed to just one would have been obvious to one having ordinary skill in the art. In addition, as noted above, Applicant's argument regarding the piezoelectric transducer is also moot, as any transducer is capable of changing the amplitude of oscillations.

With respect to Applicant's argument that Bory does not teach a protruding treatment element through a second opening, it is again noted that Bory has formed the basis of an 'obviousness' rejection, and Examiner has deemed that it would have been obvious to have a treatment element protrude from a treatment device.

Applicant's arguments with regard to Munch and Chiarizzio are moot, as they do not raise distinct issues from those already discussed.



***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **TARUN K. SRIVASTAVA** whose telephone number is (571)270-3769. The examiner can normally be reached on **M - F 5:30 - 2:00 EST**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Cris Rodriguez** can be reached on **571-272-4964**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/John J Wilson/  
Primary Examiner  
Art Unit 3732**

Respectfully,  
TKS  
/T. K. S./  
Examiner, Art Unit 3732  
11/05/2008